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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,156	10/11/2005	Andreas Meinke	05-747	4561

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,156	MEINKE ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-68* is/are pending in the application.

4a) Of the above claim(s) *39,42,47 and 49-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38, 40, 41, 43-46 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 4/3/07 is acknowledged and entered.

Status of claims

2. Claims 38-68 are pending.
Claims 38, 41, 43 have been amended
Claims 38, 40, 41, 43-46 and 48 are currently under examination. However applicant states that claim 40 is withdrawn. The examiner understands it is an oversight made in the response and included the claim 40 to elected invention as the claim is not withdrawn by the examiner..
Claims 39, 42 and 47 , 49-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions M.P.E.P § 821.03.

Claim Rejections - 35 USC 101 withdrawn

3. In view of amendment to claim 38, the rejection made under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC § 112, second paragraph withdrawn

4. In view of amendment to claims , the rejection under 35 U.5.C. 112, second paragraph is withdrawn.

Claim Rejections - 35 USC 102 withdrawn

5. In view of amendment to claim 38, the rejection of claim 38 under 35 U.S.C. 102 (b) as being anticipated by Mc Cool is withdrawn.

Claim Rejections - 35 USC 112, first paragraph maintained

6. The written description rejection of claims 38, 41, 43-46 and 48 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

Applicant 4/3/07 argues that claims have been amended to recite the defined fragments by the particular amino acid sequences and subsequences and are disclosed in their specification. Applicant cites for example, the specification discloses numerous fragments of SEQ ID NO: 243 (inter alia, on p. 12; Table 1 (on p. 73) and Table 2 (on p. 80)). The specification further provides a definition of term "fragments" (p. 23, paragraphs 2 and 3; p. 24, paragraphs 5, 6 & 7), and provides methods to make (e.g., p. 31, paragraph 6) and select appropriate (antigenic) fragments (e.g., p. 24, paragraphs 5, 6, 7), as well as methods to identify relevant amino acids (e.g., p. 33). In addition, the specification discloses possible substitutions that can be made within SEQ ID NO: 243 to maintain its antigenicity (e.g., p. 20, paragraph 6 and p. 23, last paragraph), predicted immunogenic amino acids (p. 30, paragraph 1 and 2; Table 1 on

page p. 73) and serum reactive epitopes (Table 2, p. 80). Accordingly, the specification discloses structural features common to members of the species and features that constitute a sufficiently substantial portion of the genus.

The argument has been considered but has not been found persuasive because claim 38 does not comprises defined fragments rather comprises a fragment without any identifying characteristics associated with function. Further , the cited fragments in the specification appears to be isolated and purified antigenic fragments consisting amino acid 4-25, ----or 236-258 of SEQ.ID.NO:243 . However, the claimed fragments comprise structural characteristic such as defined amino acid residues from position 4-25, 52-67 etc but lack functional characteristics because they do not have a common function that constitute a sufficient portion of the genus as all members maintain the same antigenicity. Therefore, these fragments cannot be distinguished from each other.

7. The scope of enablement rejection of claims 38, 40, 41, 43-46 and 48 under 35 U.S.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

Applicant 4/3/07 argues that claims have been amended to recite the defined fragments by the particular amino acid sequences and subsequences and are disclosed in their specification. Applicant cites for example, the specification discloses numerous fragments of SEQ ID NO: 243 (inter alia, on p. 12; Table 1 (on p. 73) and Table 2 (on p. 80)). The specification further provides a definition of term "fragments" (p. 23, paragraphs 2 and 3; p. 24, paragraphs 5, 6 & 7), and provides methods to make (e.g., p. 31, paragraph 6) and select appropriate (antigenic) fragments (e.g., p. 24, paragraphs 5, 6, 7), as well as methods to identify relevant amino acids (e.g., p. 33). In addition, the specification discloses possible substitutions that can be made within SEQ ID NO: 243 to maintain its antigenicity (e.g., p. 20, paragraph 6 and p. 23, last paragraph), predicted immunogenic amino acids (p. 30, paragraph 1 and 2; Table 1 on page p. 73) and serum reactive epitopes (Table 2, p. 80).

The argument has been considered but has not been found persuasive because, the cited fragments in the specification appears to be isolated and purified antigenic fragments consisting amino acid 4-25, ----or 236-258 of SEQ.ID.NO:243 . However, the claimed fragments are not the same as argued. Therefore, the rejection is maintained for the reasons set forth above.

Claim Rejections - 35 USC 102 maintained

8. The rejection of claims 38, 40, 41, 43-45 and 48 under 35 U.S.C. 102(b) as being anticipated by Masignani et al publication number WO 200277021 (WO 02/077021) is maintained for the same reasons as set forth in the previous office action.

Applicant states that claim 40 is withdrawn. However claim 40 is not withdrawn by the examiner. Clarification is required.

Applicant argues 4/3/07 that Masignani reference discloses an isolated S. pneumoniae antigen with SEQ ID NO: 4652 that is 100% identical to the claimed SEQ ID NO: 243 but the amino acid sequence is an open reading frame of S. pneumoniae genomic DNA without disclosing whether in fact this polypeptide is actually produced by the bacteria. Moreover, the reference fails to disclose that the putative polypeptide is antigenic. Further, the Masignani reference fails to provide any teaching with regard to peptide fragments, particularly fragments that could produce protective immune response.

The argument has been considered but has not been found persuasive because the disclosed protein is a from Streptococcus pneumoniae, type 4 strain and is 100% identical to the claimed protein as shown below. The polypeptide is antigenic as it contains more than 10 amino acid long and it is routine in the art of immunology that peptides as small as 5-8 amino acids induce an immune response. Therefore, the polypeptide with 392 amino acids is antigenic and comprise fragments that are antigenic. The argument "protective" is not set forth in the claim. Therefore, the rejection is maintained.

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Streptococcus pneumoniae; type 4 strain.

ABU02747 standard; protein; 392 AA.

  Query Match             100.0%;  Score 1927;  DB 6;  Length 392;
  Best Local Similarity   100.0%;  Pred. No. 1.1e-127;
  Matches  392;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

       Qy          1 MKKKILASLLLSTVMVSQVAVLTTAHAETTDDKIAAQDNKISNLTAQQQEAQKQVDQIQE 60
                     ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
       Db          1 MKKKILASLLLSTVMVSQVAVLTTAHAETTDDKIAAQDNKISNLTAQQQEAQKQVDQIQE 60

       Qy         61 QVSAIQAEQSNLQAENDRLQAESKKLEGEITELSKNIVSRNQSLEKQARSAQTNGAVTSY 120
                     ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
       Db         61 QVSAIQAEQSNLQAENDRLQAESKKLEGEITELSKNIVSRNQSLEKQARSAQTNGAVTSY 120

       Qy        121 INTIVNSKSITEAISRVAAMSEIVSANNKMLEQQKADKKAISEKQVANNDAINTVIANQQ 180
                     ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
       Db        121 INTIVNSKSITEAISRVAAMSEIVSANNKMLEQQKADKKAISEKQVANNDAINTVIANQQ 180

       Qy        181 KLADDAQALTTKQAELKAAELSLAAEKATAEGEKASLLEQKAAAEAEARAAAVAEAAYKE 240
                     ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
       Db        181 KLADDAQALTTKQAELKAAELSLAAEKATAEGEKASLLEQKAAAEAEARAAAVAEAAYKE 240

       Qy        241 KRASQQQSVLASANTNLTAQVQAVSESAAAPVRAKVRPTYSTNASSYPIGECTWGVKTLA 300
                     ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
       Db        241 KRASQQQSVLASANTNLTAQVQAVSESAAAPVRAKVRPTYSTNASSYPIGECTWGVKTLA 300

       Qy        301 PWAGDYWGNGAQWATSAAAAGFRTGSTPQVGAIACWNDGGYGHVAVVTAVESTTRIQVSE 360
                     ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
       Db        301 PWAGDYWGNGAQWATSAAAAGFRTGSTPQVGAIACWNDGGYGHVAVVTAVESTTRIQVSE 360

       Qy        361 SNYAGNRTIGNHRGWFNPTTTSEGFVTYIYAD 392
                     ||||||||||||||||||||||||||||||||
       Db        361 SNYAGNRTIGNHRGWFNPTTTSEGFVTYIYAD 392
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Relevant Prior Art

9. The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

Lapez (Int Microbiol. 2004 Sep; 7(3): 163-71) teach Streptococcus pneumoniae (pneumococcus), a bacterium with a long biological pedigree, best illustrates the rapid evolution of antibiotic resistance, which has led to major public health concerned discusses the molecular basis of the two main virulence factors of pneumococcus, the capsule and cell-wall hydrolases, as well as new approaches to developing medicinal weapons for preventing pneumococcal infections. In addition, current knowledge regarding pneumococcal phages as potential contributors to virulence and the use of lytic enzymes encoded by these phages as therapeutic tools is reviewed.
Fleck RA, (Clinical and Diagnostic Laboratory Immunology, January 2005, p. 19-27, Vol. 12, No. 1) teaches *Streptococcus pneumoniae* is an important bacterial pathogen responsible for sepsis, meningitis, pneumonia, and otitis media. Antibodies to pneumococcal capsular polysaccharide (PS) protect the host by opsonizing pneumococci for phagocytosis by granulocytes and macrophages, and this opsonizing potential has also been associated with vaccine-induced immunoprotection
Klugm et al Emerg Infect Dis. 2005 Jun; 11(6): 802-7 teach
the emergence of multidrug resistance in pneumococci has largely been focused on penicillin-resistant Streptococcus pneumoniae. Macrolide antimicrobial drugs have been widely used to empirically treat community-acquired RTIs because of their efficacy in treating both common and atypical respiratory pathogens, including S. pneumoniae. However, increased macrolide use has been associated with a global increase in pneumococcal resistance, which is leading to concern over the continued clinical efficacy of the macrolides to treat community-acquired RTIs. The art provides an overview of macrolide-resistant S. pneumoniae and assess the impact of this resistance on the empiric treatment of community.
Hoffman et al (Pediatrics. 2003 Nov; 112(5): 1095-102) teach Streptococcus pneumoniae infections in the neonate (SPIN) are relatively unusual events (1%-11% of neonatal sepsis) but are associated with substantial morbidity and mortality. Previous reports suggest that invasive SPIN is associated with prolonged rupture of membranes, maternal colonization/illness, prematurity, early-onset pneumonia presentation (<72 hours), and high mortality (50%). Twenty-nine cases of SPIN were identified from a total of 4428 episodes of S pneumoniae infection in children. Sixty-six percent were male, and 55% were white; the mean age was 18.1 day (+/-8.2). Ninety percent of infants were >or 38 weeks' gestation. Two mothers had bacterial infections at delivery; 1 had S pneumoniae isolated from both blood and cervix, and 1 had clinical amnionitis. The primary diagnoses in the neonates were bacteremia meningitis bacteremic pneumonia, septic arthritis/osteomyelitis and otitis media.

Remarks

10. No claims are allowed.

This application contains claims 39, 42 and 47 , 49-68 drawn to an invention nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

11. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

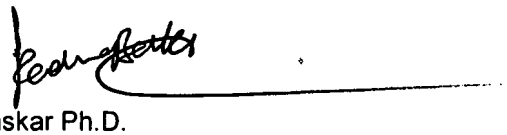
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600



Padma Baskar Ph.D.

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER